

### Remarks

Claims 1-48, 51 and 55 are pending in this application. Claims 1-34, 43-45, 51 and 55 are rejected. No claims are amended.

### Interview Summary

Applicants thank the Examiner for the courtesy of the interview held on March 18, 2010, with attorneys for Applicants. During the interview, the rejection under 35 U.S.C. 103(a) and the cited prior art was discussed. The unexpected results detailed in "Trial 2" in the specification was also discussed.

### Rejection Under 35 U.S.C. § 103(a)

The present invention relates to a composition comprising:

- at least one frozen antigenic medium; and
- at least one frozen adjuvant;

wherein the composition is in a solid state, and

wherein the at least one frozen antigenic medium and the at least one frozen adjuvant each comprise one or more phases which are distinct from each other; and

wherein the composition would be in the liquid state at a temperature greater than or equal to 4°C.

The present invention is aimed at developing vaccines which can be stored for several years and which are ready for use after thawing.

Claims 1-34, 43-45, 51, and 55 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) by U.S. Patent No. 6,251,407 to Ganne ("Ganne") in view of Salt, and U.S. Patent Application No. 2002/0058040 to Grimes et al. ("Grimes").

The *Prima Facie* Case

Applicants respectfully submit that Ganne does not preclude patentability under 35 U.S.C. 103(a), pursuant to 35 U.S.C. § 103(c). Section 103(c) states:

(c)(1) Subject matter developed by another person, which qualifies as prior art only under one or more of sections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The present application was filed July 29, 2003, is a divisional of U.S. Application No. 09/972,841, filed October 2001, and claims priority to French Application No. FR0012817, filed October 6, 2000. The present application is assigned to Societe d'Exploitation de Produits pour les Industries Chimique.

U.S. Patent No. 6,251,407 ("Ganne"), filed June 6, 1997, and issued June 26, 2001, is a divisional of U.S. Application No. 08/478,091, filed June 7, 1995, and claims priority to French Application No. FR 95 04739, filed April 20, 1995. Ganne is also assigned to Societe d'Exploitation de Produits pour les Industries Chimique.

Accordingly, Applicants respectfully submit that Ganne is 102(e) prior art only with respect to the present application.

Statement of Common Ownership

The present application and U.S. Patent No. 6,251,407 ("Ganne") were, at the time the invention of the present application was made, owned by or subject to an obligation of assignment to Societe d'Exploitation de Produits pour les Industries Chimique.

For at least this reason, Applicants submit this rejection is improper and should be withdrawn.

Unexpected Results

As discussed during the interview, Applicants submit that the claimed composition is also non-obvious by virtue of the unexpected results observed by Applicants. In "Trial 2" described in the specification at pp. 23-24, a composition according to the invention (A<sub>4</sub>) was compared to a conventional composition (B<sub>4</sub>) after storage for 7 months at - 20 °C. The table at the top of page 24 of the specification shows a comparison of percent of animals protected for A<sub>4</sub> and B<sub>4</sub> compositions at increasing dilutions:

Compositions	Dilution of the compositions				
	none	1/3	1/9	1/27	1/81
A <sub>4</sub>	100%	100%	100%	100%	75%
B <sub>4</sub>	100%	100%	100%	75%	25%
P <sub>4</sub>	0%				

The specification states with reference to "Trial 2:"

This trial showed that a vaccine composition, comprising, in the solid state, an antigenic phase and an adjuvant phase which are distinct in relation to each other...when used after a 7-month storage at 20°C., is more effective than a vaccine composition containing the same constituents but which was stored for the same period and at the same temperature in the form of an emulsion (froze) [sic] of the various phases.

Specification at p. 24, lines 5-11.

Applicants respectfully submit that it would be expected that the composition of the invention would have the same effectiveness at higher dilution when compared to an emulsion of the same components; however, as shown in Trial 2, a significant difference is observed. Indeed, the substantially greater effectiveness of the composition according to the invention at higher dilution is both a beneficial and completely unexpected result as compared to the closest prior art. Therefore, Applicants again respectfully submit that this rejection should be withdrawn.

Conclusion

An indication of allowance of all claims is respectfully solicited. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,  
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